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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,112	07/07/2004	Robert J Benkowski	0021906.023US	5620
22904 7590 12/12/2007 LOCKE LORD BISSELL & LIDDELL LLP ATTN: IP DOCKETING 600 TRAVIS SUITE 3400 HOUSTON, TX 77002-3095			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,112

Applicant(s)

BENKOWSKI ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Newly submitted claims 16-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the newly presented combination as claimed does not require the particulars of the original subcombination as claimed because the combination does not require using a predetermined speed. The subcombination has separate utility such as a method to control a VAD not requiring monitoring the patients heart rate but being solely operated based on the patients diastolic VAD flow rate.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-18 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 7, 8, 10, 11, 14, 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagyszalancyzy et al (6048363). Nagyszalancyzy discloses a blood pump that continuously monitors during systole and diastole the flow rate and increases or decrease the pump speed based on the flow rate to achieve the proper pump operating point (e.g. columns 14-16, table 1, figures 22 and 23, etc.) and therefore will monitor diastolic pump flow and change the speed in response to the flow. For claims 14, 15, 19, and 20, Nagyszalancyzy describes (e.g. columns 13-15) the use of setting the predetermined speed in accordance with activities such as sleeping and the implantable pressure sensor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 6, 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagyszalancyzy. Nagyszalancyzy discloses the claimed invention except for monitoring

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the heart rate and changing/increasing the pump speed also in response to the changing/increasing heart rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pump system and method as taught by Nagyszalanczy, with monitoring the heart rate and changing/increasing the pump speed also in response to the changing/increasing heart rate since it was known in the art that pump systems and methods monitor the heart rate and change/increase the pump speed also in response to the changing/increasing heart rate in order to provide a conventional and easily implemented way to monitor the patients increased demand and provide the proper amount of pressure/flow/pumped blood to the patient based on the patients increased activity, such as exercising, walking, etc.

Response to Arguments

Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. The argument that the "diastolic VAD flow rate is considered herein as the VAD flow contribution below the mean VAD flow rate" and that Nagyszalanczy does not teach monitoring or receiving the diastolic flow rate as a function of the mean flow rate is not persuasive for three reasons. First, the "mean flow rate" is not used as a claim limitation. Second, unless the specification specifically and clearly sets forth that a special definition for a term is to be applied to the claims, that term is to be given its broadest reasonable interpretation. Since the specification does not specifically and clearly set forth a special definition for "diastolic VAD flow rate" the term has been given its broadest reasonable interpretation. It is suggested to specifically claim how the diastolic VAD flow rate is measured in comparison to the mean flow rate. Finally, since Nagyszalanczy continuously monitors the flow rate during systole and diastole to continuously change the speed of the pump he will/does measure the

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VAD flow contribution below the mean VAD flow rate and change the speed based on the diastolic VAD flow rate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
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